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**REMARKS**

Claims 1 – 31 are pending in the application. Claims 13 - 24 have been canceled as being drawn to a non-elected invention. Claims 1, 2, 3, 6, 8, 11, 12, and 28 - 31 have been amended. New claims 32 and 33 have been added. No new matter has been added by virtue of the new claims or amendments, support being found throughout the specification and the claims as originally filed.

**Objections**

The Examiner has objected to the Information Disclosure Statement (IDS) filed on November 18, 2004 for allegedly failing to comply with 37 CFR 1.98 (a)(2). Applicants are submitting a replacement IDS under separate cover.

The Examiner has objected to claims 8, 11, 12, and 29 for minor informalities. Applicants have made appropriate spelling and grammar corrections and respectfully request withdrawal of the objection.

Applicants thank Examiner Johannsen for her time discussing the instant application in the telephonic interview conducted on August 29, 2007.

**Claim Rejections****35 U.S.C. §112, second paragraph**

The Examiner has rejected claims 1 – 12 and 25 – 31 under 35 USC §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse the rejection.

The Examiner argues "claims 1 – 12 and 25 – 31 are indefinite over the recitation of the limitation 'suitable for the detection, identification and/or quantitation of *Pseudomonas (sensu stricto)*' in claim 1." (Office Action, p. 3 – 4). Applicants

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have amended claim 1 to remove the "suitable" language. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

The Examiner argues that claims 1 – 12 and 25 – 31 "are indefinite over the recitation of the language 'said PNA probe being complementary to a target sequence of 23S rRNA or rDNA of all species of the genus *Pseudomonas*, or its complement.'" (Office Action, p.4). The Examiner alleges "the specification makes clear, via the use of the language 'essentially all'...species and the exclusion of at least one particular species, that the language 'all species of the genus *Pseudomonas*' does not in fact include all species of the genus *Pseudomonas*, such that the language of the claims has a meaning contrary to its ordinary meaning." (Office Action, p.4). The Examiner argues further "in the instant case, the language 'all species of the genus *Pseudomonas*' is indefinite because the specification does not clearly redefine the language." (Office Action, p. 4 – 5). Applicants disagree.

Applicants provide, at paragraph [0028], a definition of the phrase "all species of the genus *Pseudomonas*" as follows:

Reference herein to "all species of the genus *Pseudomonas*", or a related phrase means essentially all species of that genus described in the "Approved lists of bacterial names." Int. J. Syst. Bacteriol. (1980) 30:225-420 with subsequent revisions published in Int. J. Syst. Bacteriol. with the exception of *Pseudomonas pertucinogena* (**see Example 2**) [emphasis added]

Moreover, in the Examples, Applicants further exemplify the meaning of the phrase 'all species of the genus *Pseudomonas*', and support the exclusion of the particular *Pseudomonas pertucinogena* species:

The results show that PNA probe provides accurate identification of *Pseudomonas* species only, whereas other species including *Pseudomonas*-like species were all negative.  
[0126]

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According to Table 1, *Pseudomonas pertucinogena* was not detected by the PNA probe. This species belongs to the *Pseudomonas pertucinogena* group, where the other group member *Pseudomonas denitrificans* has been excluded from the *Pseudomonas* genus (Rejection of the species name *Pseudomonas denitrificans* (Christensen) Bergey et al. 1923."Int. J. Syst. Bacteriol. (1982) 32:466). Other studies have shown that *Pseudomonas pertucinogena* is closely related with *Bordetella* species and may therefore not belong in the *Pseudomonas* genus. Even if it is, it is also believed that presence of *Pseudomonas pertucinogena* in a sample used to practice the invention would be rare at best. Thus, the "false negative" shown in Table 1 above is not believed to have any significance and should not be construed to limit the invention in any way. [0127]

Thus, the language "all species of the genus *Pseudomoas*" is not indefinite. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

The Examiner has rejected claims 1 – 12 and 25 – 36 for alleged indefiniteness. The Examiner argues "it is not clear what the limitation 'its complement' in claim 1 refers to." (Office Action, p.5). Applicants respectfully traverse the rejection. Applicants have amended claim 1 to further clarify what the limitation "its complement" refers to.

The Examiner has rejected claim 2 as being "indefinite over the recitation of the limitation 'at least about 90% identical.'" (Office Action, p.5). The Examiner argues that "the term 'about' raises doubt about whether molecules with a lower % identity are encompassed by the claim, and if so, what the actual cut-off for the claim is." (Office Action, p.5). Applicants have amended the claim to remove the "about" language.

The Examiner has rejected claim 3 as being 'indefinite over the recitation of the limitation 'the probe sequence' because there is insufficient antecedent basis

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for this limitation." (Office Action, p.6). Applicants have amended claim 3 to correct the antecedent basis.

The Examiner has rejected claim 3 as being 'indefinite over the recitation of the limitation '8 – 17 subunits in length' because it is not clear what would constitute a subunit within the context of the claims." (Office Action, p.6). Applicants have amended the claim to recite "nucleobase subunit." The specification teaches at paragraph [0025] that **"a PNA subunit consists of a naturally occurring or non-naturally occurring nucleobase attached to the aza nitrogen of the N-[2-(aminoethyl)]glycine backbone through a methylene carbonyl linkage."**

The Examiner has rejected claim 6 as being 'indefinite over the recitation of the limitation 'the detectable moiety or moieties' because there is insufficient antecedent basis for this limitation." (Office Action, p.6). Applicants disagree. Claim 6 depends from claim 5, which recites "(t)he PNA probe of claim 1, wherein the probe is labeled with at least one detectable moiety." Thus, claim 6 recites proper antecedent basis.

The Examiner has rejected claim 12 as being 'indefinite over the recitation of the limitation 'wherein in situ hybridization is used for analysis of Pseudomonas (sensu stricto) optionally present in the sample.'" (Office Action, p.6). The Examiner alleges that "(f)irst, there is insufficient antecedent basis for the limitation 'the sample.' Second, as claim 1 is drawn to a particular product, it is unclear how the recitation of claim 12 might be further limiting." (Office Action, p.6). Applicants respectfully traverse the rejections.

Instant claim 12 recites "(t)he PNA probe of claim 1, wherein in situ hybridization is used for analysis of Pseudomonas (sensu stricto). Claim 12 has been amended to no longer recite the limitation "the sample." The specification teaches that other methods can be used for the analysis of Pseudomonas, for example PCR. At paragraph [0019] the specification teaches "(t)hose of ordinary skill in the art will also appreciate that the complement probing sequence is equally

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suitable for assays, such as but not limited to real-time PCR, that are using rDNA as a target. Accordingly, Applicants respectfully request withdrawal of the rejection.

The Examiner has rejected claims 28 - 31 as being 'indefinite because the claims refer to the claimed kits being 'adapted' for use in particular methods/ assays, but do not indicate, e.g., what adaptations are actually made, as would be necessary to apprise one of skill in the art as to what differences in structural and/or functional properties actually exist with respect to the claimed kits as compared to prior art kits." (Office Action, p.6).

Applicants have amended the claims to remove the "adapted" language.

In view of the above amendments and remarks, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph and allowance of the claims.

**35 U.S.C. §112, first paragraph-written description**

The Examiner has rejected claims 1 - 12 and 25 - 31 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

Instant claim 1 recites a PNA probe comprising a nucleobase sequence for the detection, identification and/or quantitation of *Pseudomonas* (*sensu stricto*), said PNA probe being complementary to a target sequence of 23S rRNA or rDNA of all species of the genus *Pseudomonas*, or sequences complementary to the target sequence.

The Examiner argues, "a clear description of what is encompassed by the language of the claims is not provided. Specifically, the specification never makes clear what species and/or what 23S rRNA/rDNA sequences are actually encompassed by the claims." (Office Action, p.8). The Examiner alleges "the specification does not attempt to incorporate by reference, e.g., the reference or revisions mentioned on page 8." (Office Action, p.8). Applicants disagree.

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As described above, and reemphasized here, Applicants have clearly provided description of the identities of the species encompassed by the language of the claims. Applicants again direct the Examiner to the specification, first to the definition of the phrase "all species of the genus *Pseudomonas*" at paragraph [0028] (see above). The definition clearly states **"the exception of *Pseudomonas pertucinogena*"** and in the Examples, Applicants support this exception. Applicants refer the Examiner to the Table at paragraph [0125] of the published application, shown below:

Species	ATCC#	Results
<i>Acinetobacter calcoaceticus</i>	14987	Negative
<i>Aeromonas hydrophila</i>	7965	Negative
<i>Brevundimonas diminuta</i>	19146	Negative
<i>Burkholderia cepacia</i>	25416	Negative
<i>Comamonas testosteroni</i>	17409	Negative
<i>Delftia acidovorans</i>	15668	Negative
<i>Pseudomonas aeruginosa</i>	9027	Positive
<i>Pseudomonas aeruginosa</i>	27853	Positive
<i>Pseudomonas alcaligenes</i>	14909	Positive
<i>Pseudomonas chlororaphis</i>	9446	Positive
<i>Pseudomonas fluorescens</i>	17397	Positive
<i>Pseudomonas fluorescens</i>	13525	Positive
<i>Pseudomonas fragi</i>	4973	Positive
<i>Pseudomonas huttiensis</i>	14670	Positive
<i>Pseudomonas luteola</i>	35563	Positive
<i>Pseudomonas mendocina</i>	25411	Positive
<i>Pseudomonas mucidolens</i>	4685	Positive
<i>Pseudomonas nitroreducens</i>	33634	Positive
<i>Pseudomonas pertucinogena</i>	190	Negative
<i>Pseudomonas pseudoalcaligenes</i>	12815	Positive

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<i>Pseudomonas putida</i>	12633	Positive
<i>Pseudomonas putida</i>	17484	Positive
<i>Pseudomonas stutzeri</i>	11607	Positive
<i>Pseudomonas veronii</i>	700474	Positive
<i>Ralstonia pickettii</i>	27511	Negative
<i>Sphingomonas paucimobilis</i>	29837	Negative
<i>Stenotrophomonas maltophilia</i>	13637	Negative

According to the results shown in Table, the "PNA probe provides accurate identification of *Pseudomonas* species only, whereas other species including *Pseudomonas*-like species were all negative." (Paragraph [0126]). As taught by the specification at paragraph [0127], *Pseudomonas pertucinogena* "belongs to the *Pseudomonas pertucinogena* group, where the other group member *Pseudomonas denitrificans* has been excluded from the *Pseudomonas* genus (Rejection of the species name *Pseudomonas denitrificans* (Christensen) Bergey et al. 1923." *Int. J. Syst. Bacteriol.* (1982) 32:466). Other studies have shown that *Pseudomonas pertucinogena* is closely related with *Bordetella* species and may therefore not belong in the *Pseudomonas* genus. Even if it is, it is also believed that presence of *Pseudomonas pertucinogena* in a sample used to practice the invention would be rare at best. Thus, the "false negative" shown in Table 1 above is not believed to have any significance and should not be construed to limit the invention in any way." The data and description clearly support language of "the exception of *Pseudomonas pertucinogena*" in the definition.

Finally, the specification clearly incorporates the references cited.

Applicants direct the Examiner to paragraph [0131] of the specification:

The disclosures of all references mentioned herein are incorporated by reference."

Accordingly, Applicants respectfully request withdrawal of the written description requirement and allowance of the claims.

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**35 U.S.C. §112, first paragraph-enablement**

The Examiner has rejected claims 1 – 12 and 25 – 31 under 35 USC §112, first paragraph, for lack of enablement. The Examiner alleges that "the specification, while being enabling for a PNA probe consisting of SEQ ID NO:1, does not reasonably provide enablement for any probe 'complementary to a target sequence of 23S rRNA or rDNA of all species of the genus *Pseudomonas*.'" (Office Action, p.9). Applicants respectfully traverse the rejection.

Instant claim 1 recites a PNA probe comprising a nucleobase sequence for the detection, identification and/or quantitation of *Pseudomonas* (sensu stricto), said PNA probe being complementary to a target sequence of 23S rRNA or rDNA of all species of the genus *Pseudomonas*, or sequences complementary to the target sequence. Instant claim 2 depends on the PNA probe of claim 1, wherein at least a portion of the probe is at least 90% identical to the nucleobase sequence or complement thereof selected from the following sequence: CCT ACC ACC TTA AAC (SEQ ID NO: 1).

The MPEP states that the determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing a combination of factual considerations: the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples, and the quantity of experimentation necessary. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. Accordingly, the Examiner must consider the above factors in his rejection.

The Examiner again argues "the claims encompass probes complementary to 'a target sequence of 23S rRNA or rDNA of all species of the genus *Pseudomonas*.'" (Office Action, p.10). The Examiner argues further that the



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specification makes clear, via the use of the language 'essentially all' (rather than simply 'all') species and the exclusion of at least one particular species, that the language 'all species of the genus *Pseudomonas* does not in fact include all species of the genus *Pseudomonas*, such that the language of the claims has a meaning contrary to its ordinary meaning." (Office Action, p.10). The Examiner alleges that "a clear description of what is encompassed by the language of the claims is not provided (and) the specification never makes clear what species and/or what 23S rRNA/rDNA sequences are actually encompassed by the claims." Applicants disagree.

As pointed out in detail above, Applicants have clearly set forth a clear description of what is encompassed by the language of the claims. As shown in Table 1 and the Examples above, Applicants have clearly shown what species and/or what 23S rRNA/rDNA sequences are actually encompassed by the claims.

The Examiner argues further that "the specification does not disclose and exemplify the use of a single PNA probe having the sequence set forth in SEQ ID NO: 1, such that one of skill in the art could make and use this particular probe." (Office Action, p.11). Applicants disagree. Applicants point the Examiner again to the Examples, specifically to paragraphs [0123] – [0124], which specifically describes use of the PNA probe of SEQ ID NO: 1 targeting *Pseudomonas*:

Smears were covered with approximately 50 .mu.L of hybridization solution containing 10% (w/v) dextran sulfate (Sigma Chemical Co., St. Louis, Mo.), 10 mM NaCl (J. T. Baker), 30% (v/v) formamide (Sigma), 0.1% (w/v) sodium pyrophosphate (Sigma), 0.2% (w/v) polyvinylpyrrolidone (Sigma), 0.2% (w/v) ficoll (Sigma), 5 mM Na.sub.2EDTA (Sigma), 1% (v/v) Triton X-100 (Aldrich), 50 mM Tris/HCl pH 7.5 and 500 nM fluorescein-labeled **PNA probe (Flu-OO-CCTACCACCTTAAAC)** targeting *Pseudomonas* (sensu stricto). Coverslips were placed on the smears to ensure even coverage with hybridization solution, and the slides were subsequently placed on a slide warmer with a humidity chamber (Slidemoat, Boeckel, Germany) and

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incubated for 90 min at 50.degree. C. Following hybridization, the coverslips were removed by submerging the slides into approximately 20 mL/slide pre-warmed 5 mM Tris, pH 10, 15 mM NaCl (J. T. Baker), 0.1% Triton X-100 (Aldrich) in a water bath at 50.degree. C. and washed for 30 min. Each smear was finally mounted using one drop of Mounting Fluid and covered with a coverslip. Microscopic examination was conducted using a fluorescence microscope equipped with a FITC/Texas Red dual band filter set. *Pseudomonas* (sensu stricto) was identified as green fluorescent rods.

The results of the experiments described above are listed in Table 1, and demonstrate that the PNA probe having the sequence set forth in SEQ ID NO: 1 can be used in the invention as claimed.

Moreover, Applicants provide ample direction in the specification for one of skill in the art to make a PNA probe, for example at paragraphs [0057] – [0062]. At paragraphs [0069] – [0072], the specification teaches what would be required for one of skill in the art to determine percent homology of a probe and a *Pseudomonas* target sequence.

Taken together, the teachings of the specification and knowledge of one of skill in the art enables one of skill in the art to practice the full scope of the claimed invention without having to resort to undue experimentation. Applicants accordingly request that the rejection be reconsidered and withdrawn.

### 35 U.S.C. §102(b)

Claims 1 – 12 and 25 – 31 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Lexow (WO 00/39333; the '333 reference herein). The Examiner argues that the '333 reference "discloses all 65,536 possible PNA octamers (and) such molecules meet the requirements of claims 1 and 3." (Office Action, p.12). Applicants respectfully traverse the rejection.

Instant claim 1 recites a PNA probe comprising a nucleobase sequence for the detection, identification and/or quantitation of *Pseudomonas* (sensu stricto),

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said PNA probe being complementary to a target sequence of 23S rRNA or rDNA of all species of the genus *Pseudomonas*, or sequences complementary to the target sequence. Instant claim 3 is dependent upon the PNA probe of claim 1, wherein the PNA probe comprises a sequence of 14-17 nucleobase subunits in length.

The teachings of the '333 reference do not anticipate the claimed invention. Specifically, the '333 reference does not teach or suggest use of the octamer probes of the invention for the detection, identification and/or quantitation of *Pseudomonas* (*sensu stricto*), where the probe is a PNA probe that is complementary to a target sequence of 23S rRNA or rDNA of all species of the genus *Pseudomonas*, or sequences complementary to the target sequence. Moreover, as pointed out by the Examiner, the '333 reference only teaches PNA **octamers**. The instant claims are directed to PNA probes comprising a sequence of 9-17 nucleobase subunits in length. The instant specification provides support for PNA probes with a length that is "preferably less than about 20 subunits", for example at paragraph [0067].

Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

### CONCLUSIONS

For the reasons provided, Applicant submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

A one month extension of time is requested.

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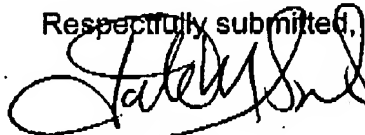
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The Director is hereby authorized to charge any credits or deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 04-1105.

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Respectfully submitted,



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